

**REMARKS / ARGUMENTS**

**1. Response to 09/25/2008 Office Action**

For the convenience of the Examiner and clarity of purpose, Assignee has reprinted the substance of the Office Action in *10-point bolded and italicized font*. Assignee's arguments immediately follow in regular font.

*Claims 21-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.*

*Claim 21 is in the passive voice and it is unclear if any positive method step recitation is being recited. It is suggested to use active voice, such as "separating and isolating the diastolic flow rate from a pump systolic flow rate and mean flow rate".*

*In claims 22 and 23 it is unclear what element is performing the functions of separating and extracting since the claim has not set forth an element to perform the function. In addition, in claim 22, the systolic flow rate has not been previously sensed to separate/extract a signal separately from it.*

Claim 21 recites the "method of claim 1, wherein the diastolic pump flow rate is isolated from a systolic flow rate and the mean flow rate". Claim 1 recites "wherein the diastolic pump flow rate is an isolated flow contribution below a mean flow rate". Thus, claim 21 merely further defines "the diastolic pump flow rate". The quoted portion of claim 1 was not rejected under 35 U.S.C. 112. Therefore, it is unclear why claim 21 has been rejected.

Similarly, claims 22 and 23 recite the "pump system of claim 7, wherein the diastolic pump flow rate is extracted separately from a systolic flow rate" and "pump system of claim 7, wherein the diastolic pump flow rate is separated out from the flow rate signal", respectively. Claim 7 recites "wherein the diastolic pump flow rate is a flow contribution below a mean flow rate". Thus, claims 22 and 23 merely further define "the diastolic pump flow rate". The quoted portion of claim 7 was not rejected under 35 U.S.C. 112. Therefore, it is unclear why claims 22

and 23 have been rejected.

Because claims 21-23 merely further define "the diastolic pump flow rate", correction does not appear to be required. However, Assignee is more than willing to discuss possible amendments. In this regard, the Examiner is encouraged to contact the undersigned.

*Claims 1, 3, 5, 7, 8, 10, 11, 14, 15, 19, and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Nagyszalanczy et al (6048363). Nagyszalanczy discloses a blood pump that uses a sensor to continuously monitor a pump parameter during systole and diastole. Nagyszalanczy monitors/extracts (computes, determine by calculation, pulls out, etc) the flow rate from the sensor signal to increase or decrease the pump speed based on the flow rate to achieve the proper pump operating point (e.g. columns 14-16, table 1, figures 22 and 23, etc.). Therefore Nagyszalanczy will monitor/extract diastolic pump flow rate contribution below a mean flow rate and change the speed in response to the flow since he measures the flow rate all through diastole, both above and below the mean diastolic flow rate. For claims 14, 15, 19, and 20, Nagyszalanczy describes (e.g. columns 13-15) the use of setting the predetermined speed in accordance with activities such as sleeping and the implantable pressure sensor. NOTE—the claims do not state that the mean flow rate is calculated based on the flow rate signal (or something similar) and that the predetermined speed is changed based on the calculated mean flow rate. Finally, the definition of "extract" can mean several things, such as "to compute", "to draw forth", "to determine by calculation", "to select and copy out", "to pull something out", "to obtain something from a source", "to calculate a value", etc., which Nagyszalanczy meets. Please see the dictionary definitions from such sources as Merriam-Webster.com or from the MSN Encarta online dictionary.*

Claim 1 recites "monitoring the patient's diastolic pump flow rate, wherein the diastolic pump flow rate is an isolated flow contribution below a mean flow rate" and "changing the predetermined speed in response to the diastolic pump flow rate". Claim 1 therefore explicitly defines the term "diastolic pump flow rate" as the "isolated flow contribution below a mean flow rate". Thus, the quoted portion of claim 1 is logically and legally equivalent to "monitoring the patient's ... isolated flow contribution below a mean flow rate" and "changing the predetermined speed in response to the [isolated flow contribution below a mean flow rate]". As a result, claim 1 requires that speed change determination be made based, at least in part, on an *isolated* flow contribution, rather than a composite flow that happens to include that flow contribution.

On page 4 of the Final Office Action, the Office acknowledges that Nagyszalanczy fails to disclose “isolating/extracting/separating the diastolic flow rate from the other flow rates”. The Office argues that the diastolic flow rate would be part of a composite flow rate and that because Nagyszalanczy teaches use of the composite flow rate, he necessarily includes the diastolic flow rate, pointing to the open-ended nature of the claim.

However, as previously argued and acknowledged by the Office, nowhere does Nagyszalanczy teach *isolating* a diastolic flow rate, much less “monitoring the patient’s ... *isolated* flow contribution below a mean flow rate” or “changing the predetermined speed in response to the [*isolated* flow contribution below a mean flow rate]”, emphasis added, as claimed. While a composite flow rate would include a non-isolated diastolic flow rate, by definition, the composite flow rate is fundamentally different than the claimed “*isolated* flow contribution below a mean flow rate”, emphasis added. By requiring the speed to be changed “in response to the [*isolated* flow contribution below a mean flow rate]”, emphasis added, claim 1 simply could not be anticipated, by “changing the predetermined speed in response to” a composite flow rate. As a result, Nagyszalanczy simply cannot anticipate claim 1. For at least this reason, Assignee respectfully submits that claim 1 is patentable over the disclosure and teaching of Nagyszalanczy. Reconsideration and withdrawal of this rejection is requested.

Claim 7 recites “*extract* a diastolic pump flow rate from the blood flow rate signal”, and “vary the speed of the pump in response to the diastolic pump flow rate, wherein the diastolic pump flow rate is a flow contribution below a mean flow rate”, emphasis added. Claim 7 therefore explicitly defines the term “diastolic pump flow rate” as the “flow contribution below a

mean flow rate”. Thus, claim 7 requires the controller to “**extract** a [flow contribution below a mean flow rate] from the blood flow rate signal” and “vary the speed of the pump in response to the ... flow contribution below a mean flow rate”.

As previously argued and acknowledged by the Office, Nagyszalanczy simply does not “**extract** a ... flow contribution below a mean flow rate” or “vary the speed of the pump in response to the ... flow contribution below a mean flow rate”, emphasis added, as claimed in claim 7. While it is true that Nagyszalanczy discusses a flow rate derived from a sensor signal, as discussed above, that flow rate is a composite of a total flow rate. Nowhere does Nagyszalanczy teach extracting any portion or contribution of that flow rate, as the term “extract” is commonly understood and used in the specification, much less varying “the speed of the pump in response to the [extracted] flow contribution below a mean flow rate”.

In response, the Office refers to the definition of “extract” found at Merriam-Webster.com, reproduced below in its entirety:

1 a: to draw forth (as by research) <extract data> b: to pull or take out forcibly <extracted a wisdom tooth> c: to obtain by much effort from someone unwilling <extracted a confession>2 a: to withdraw (as a juice or fraction) by physical or chemical process b: to treat with a solvent so as to remove a soluble substance3: to separate (a metal) from an ore4: to determine (a mathematical root) by calculation5: to select (excerpts) and copy out or cite

The Office also refers to the definition of “extract” found at the MSN Encarta online dictionary, reproduced below in its entirety:

1. pull something out: to pull something out, often using force
  - *have a tooth extracted*
2. obtain something from source: to obtain something from a source, usually by separating it out from other material
  - *a few snippets of information that I managed to extract from the conversation*
3. get something by force: to obtain something from somebody who is unwilling to give it, often by using force or threats
  - *extracted a confession from him*
4. copy passage of text: to copy or remove a passage from a text

- *This scene is extracted from the author's memoirs.*
- 5. derive pleasure from something: to obtain pleasure or enjoyment from something
- 6. CHEMISTRY INDUSTRY take something out of compound: to obtain a substance from a compound, in solid, liquid, or gas form, by using an industrial or chemical process
- 7. MATHEMATICS find root of number: to calculate the value of the root, e.g. the square root or cube root, of a number

Thus, as the Office notes, the term “‘extract’ can mean several things, such as ‘to compute’, ‘to draw forth’, ‘to determine by calculation’, ‘to select and copy out’, ‘to pull something out’, ‘to obtain something from a source’, ‘to calculate a value’, etc.” However, the Office does not explain how Nagyszalanczy’s composite flow rate teaches or otherwise meets any definition of “*extract* a [flow contribution below a mean flow rate]”, emphasis added, as claimed. Rather, Assignee asserts that Nagyszalanczy’s use of a composite flow rate actually teaches away from any applicable definition of “*extract* a [flow contribution below a mean flow rate]”, and certainly teaches away from any definition that could possibly be supported by the instant specification and claims. For example, the instant specification recites, emphasis added:

[0031] Therefore, the conventional definitions for systolic flow and diastolic flow must be modified to make them applicable to patients implanted with left VADs. Thus, the systolic flow rate is considered herein as the flow contribution above the mean flow rate value, while **the diastolic VAD flow rate is considered herein as the VAD flow contribution below the mean VAD flow rate**. Peak systolic VAD flow rate is considered herein to be the maximum VAD flow rate value in the VAD flow rate waveform in one cardiac cycle and average peak systolic VAD flow rate is the average value of multiple peak systolic VAD flow rate values over several cardiac cycles. Similarly, peak diastolic VAD flow rate is considered herein to be the minimum VAD flow rate value in the VAD flow rate waveform in one cardiac cycle and average peak diastolic VAD flow rate is the average value of multiple peak diastolic VAD flow rate values over several cardiac cycles.

[0036] The VAD flow signal 252 is ac coupled to a precision rectifier 256 to remove the mean VAD flow rate component from the analog VAD flow signal 252. **The systolic VAD flow rate 260 and diastolic VAD flow rate 261 are extracted separately.** The isolated systolic and diastolic VAD flow signals

260,261 are then low-pass filtered 262 to yield respective average peak values of the systolic and diastolic VAD flow rates. As noted herein, a patient's peak diastolic VAD flow rate or average peak diastolic VAD flow rate increases during exercise and decreases at rest. Thus, peak diastolic VAD flow rate or the average peak diastolic VAD flow rate is applied to a voltage comparator 264 to compare the signal to a predetermined threshold 266 and provide the binary indication 254 of when the patient is exercising. The pump speed may then be adjusted accordingly.

[0040] FIG. 6 is a flow diagram illustrating a physiologic control method in accordance with embodiments of the invention. The illustrated method monitors both diastolic VAD flow 301 (for example, peak diastolic VAD flow rate or average peak diastolic VAD flow rate) and heart rate 302. In block 310, the VAD flow rate is acquired, typically by receiving the VAD flow signal from the flow meter 124. In the particular embodiment illustrated, the flow signal comprises an analog voltage signal that is proportional to the VAD blood flow rate, though other implementations are envisioned in which a digital signal is received. The DC component of the signal is removed in block 312, and **the diastolic VAD flow rate is extracted from the flow signal** in block 314. This information may be processed in the manner described and illustrated in FIG. 5.

Thus, any definition of “*extract* a [flow contribution below a mean flow rate]”, actually supported by the instant specification and claims, would necessarily require “the diastolic VAD flow rate [to be drawn, pulled, separated, actually obtained, or otherwise determined] from the flow signal”.

As previously argued and acknowledged by the Office, nowhere does Nagyszalanczy teach *extracting* “a ... flow contribution below a mean flow rate”, or varying “the speed of the pump in response to the [extracted] flow contribution below a mean flow rate”, as claimed. More specifically, nowhere does Nagyszalanczy actually teach so much as determining any “flow contribution below a mean flow rate”, as claimed. While a composite flow rate would include a diastolic flow rate, by definition, the composite flow rate is fundamentally different than the claimed *extracted* “flow contribution below a mean flow rate”. By requiring the

controller to “*extract* a [flow contribution below a mean flow rate]” and “vary the speed of the pump in response to the [extracted] flow contribution below a mean flow rate”, emphasis added, claim 7 simply could not be anticipated, by any composite flow rate. As a result, Nagyszalanczy simply cannot anticipate claim 7. For at least this reason, Assignee respectfully submits that claim 7 is patentable over the disclosure and teaching of Nagyszalanczy. Reconsideration and withdrawal of this rejection is requested.

The Office also asserts that “the prior art cited with this action shows the well known use of isolating/extracting/separating the diastolic flow rate from other flow rates”. Page 5 of the Final Office Action. Of course, these references have not been made a part of an actual rejection, and therefore Assignee need not discuss each and every defect of any such rejection.

However, none of the prior art made of record teaches “monitoring the patient’s ... *isolated* flow contribution below a mean flow rate”, “changing the predetermined speed in response to the [*isolated* flow contribution below a mean flow rate]”, *extracting* “a flow contribution below a mean flow rate”, or varying “the speed of the pump in response to the [extracted] flow contribution below a mean flow rate”, emphasis added, as claimed in claims 1 and 7. For example, U.S. Patent No. 3,911,897 to Leachman appears to merely teach measuring “the duration of a diastolic period [using] an isolation rectifier”. U.S. Patent No. 4,782,817 to Singh appears to merely teach a “diastolic period” of a composite flow. While U.S. Patent Nos. 6,066,086 to Antaki, 6,395,027 to Snyder, and 6,623,420 to Reich do discuss “diastole”, none appear to include any variation of the term “diastolic flow rate”, much less any teaching of isolating or extracting the “diastolic flow rate” or using the isolated “diastolic flow rate”. Thus,

none of the prior art made of record appears to teach monitoring any isolated flow contribution, changing a pump speed in response to the isolated flow contribution, extracting a flow contribution, or varying a pump speed in response to an extracted flow contribution.

Therefore, the Office has failed to cite any prior art that teaches “monitoring the patient’s ... *isolated* flow contribution below a mean flow rate”, “changing the predetermined speed in response to the [*isolated* flow contribution below a mean flow rate]”, *extracting* “a flow contribution below a mean flow rate]”, or varying “the speed of the pump in response to the [extracted] flow contribution below a mean flow rate”, emphasis added, as claimed in claims 1 and 7. Thus, a critical element of a proper anticipation, or even obviousness, rejection is missing from the record. Furthermore, because Nagyszalanczy teaches only the use of the composite flow rate, he necessarily teaches away from “monitoring the patient’s ... *isolated* flow contribution below a mean flow rate”, “changing the predetermined speed in response to the [*isolated* flow contribution below a mean flow rate]”, *extracting* “a flow contribution below a mean flow rate]”, and/or varying “the speed of the pump in response to the [extracted] flow contribution below a mean flow rate”, emphasis added, as claimed. As a result, no combination of the prior art references made of record anticipates or obviates the currently pending claims. Reconsideration and withdrawal of these rejections is therefore requested.

*Claims 2, 4, 6, 9, 12, 13 and 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nagyszalanczy.*

Claim 21 recites “wherein the diastolic pump flow rate is isolated from a systolic flow rate and the mean flow rate”. Claim 22 recites “wherein the diastolic pump flow rate is extracted separately from a systolic flow rate”. Claim 23 recites “wherein the diastolic pump flow rate is



separated out from the flow rate signal". The claims from which claims 21-23 depend, as discussed above, both define "the diastolic pump flow rate" as a "flow contribution below a mean flow rate". Therefore, claims 21, 22, and 23, require the "flow contribution below a mean flow rate" to be isolated/extracted/separated from a systolic flow rate, mean flow rate, and/or flow rate signal.

As discussed above, on page 4 of the Final Office Action, the Office acknowledges that Nagyszalanczy fails to disclose "isolating/extracting/separating the diastolic flow rate from the other flow rates". However, the Office also asserts that "the prior art cited with this action shows the well known use of isolating/extracting/separating the diastolic flow rate from other flow rates". Page 5 of the Final Office Action. Of course, these references have not been made a part of an actual rejection, and therefore Assignee need not discuss each and every defect of any such rejection.

However, none of the prior art made of record teaches a "diastolic pump flow rate" being "isolated from a systolic flow rate and the mean flow rate", "extracted separately from a systolic flow rate", or "separated out from the flow rate signal", as claimed. For example, as discussed above, U.S. Patent No. 3,911,897 to Leachman appears to merely teach measuring "the duration of a diastolic period [using] an isolation rectifier". U.S. Patent No. 4,782,817 to Singh appears to merely teach a "diastolic period" of a composite flow. While U.S. Patent Nos. 6,066,086 to Antaki, 6,395,027 to Snyder, and 6,623,420 to Reich do discuss "diastole", none appear to include any variation of the term "diastolic flow rate", much less any teaching of isolating, extracting, or separating the "diastolic flow rate". As discussed above and acknowledged by the

Office, Nagyszalanczy fails to teach isolating, extracting, or separating the “diastolic flow rate”. Thus, none of the prior art made of record appears to teach isolating, extracting, or separating the “diastolic flow rate”.

Therefore, the Office has failed to cite any prior art that teaches isolating, extracting, or separating the “diastolic flow rate”, as claimed. Thus, a critical element of a proper obviousness rejection is missing from the record. Furthermore, because Nagyszalanczy teaches only the use of the composite flow rate, he necessarily teaches away from isolating, extracting, or separating the “diastolic flow rate”, as claimed. As a result, no combination of the prior art references made of record obviates the currently pending claims. Reconsideration and withdrawal of these rejections is therefore requested.

## **2. CONCLUSION**

Claims 1-15 and 19-23 are pending in this application. Assignee submits that each claim is patentable, as detailed herein. A notice of allowance is respectfully requested.

The Commissioner is authorized to charge to deposit account 121322/0021906.023US any other fees necessary to make this and related papers, if any, timely and effective.

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Assignee thanks the Examiner for her consideration and effort on this file. If there are any questions or if additional information is needed, the Examiner is invited to telephone or email the undersigned.

Respectfully submitted,

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